



DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2015-0371]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillators

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of 7 applications for exemptions from the cardiovascular standard [49 CFR 391.41(b)(4)]. These 7 individuals are requesting an exemption due to the presence of implantable cardioverter defibrillators (ICD) as a result of their underlying cardiac condition. If granted, the exemptions would enable these individuals with ICDs to operate commercial motor vehicles (CMVs) in interstate commerce for up to 2 years.

DATES: Comments must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA-2015-0371 using any of the following methods:

- **Federal eRulemaking Portal:** Go to www.regulations.gov. Follow the on-line instructions for submitting comments.
- **Mail:** Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE, West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.

- Hand Delivery or Courier: West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- Fax: 1-202-493-2251.

Each submission must include the Agency name and the docket ID for this Notice. Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov, at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE, Room W64-224, Washington, DC 20590-0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission. To submit your comment online, go to <http://www.regulations.gov> and in the search box insert the docket number “FMCSA-2015-0371” and click the search button. When the new screen appears, click on the blue “Comment Now!” button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this notice, or to submit your comment online, go to www.regulations.gov and in the search box insert the docket number “FMCSA-2015-0371” and click “Search.” Next, click “Open Docket Folder” and you will find all documents and comments related to the proposed rulemaking.

SUPPLEMENTARY INFORMATION:

Background

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** [49 CFR 381.315(a)]. The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The Agency may grant an exemption subject to specified terms and conditions. The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

The FMCSA provides medical advisory criteria for use by medical examiners in determining whether drivers with certain medical conditions should be certified to operate CMVs in interstate commerce. The advisory criteria are currently set out as part of the medical examination report published with 49 CFR 391.43. The advisory criteria for section 391.41(b)(4) indicate that the term “has no current clinical diagnosis of” is specifically designed to encompass:

“a clinical diagnosis of” (1) a current cardiovascular condition, or (2) a cardiovascular condition which has not fully stabilized regardless of the time limit. The term *“known to be accompanied by”* is designed to include a clinical diagnosis of a cardiovascular disease (1) which is accompanied by symptoms of syncope, dyspnea, collapse or congestive cardiac failure; and/or (2) which is likely to cause syncope, dyspnea, collapse, or congestive cardiac failure.

Summary of Applications

Ellis James Benson

Mr. Benson is a 53 year old Class A CDL holder in Minnesota. A June 2, 2015 letter from his cardiologist reports that Mr. Benson’s defibrillator was implanted on November 12, 2008. His records show that his defibrillator delivered therapies on February 27, 2014, and on February 28, 2015. In 2008 (his most recent study) showed a left ejection fraction of 55-60%.

Jon Carey

Mr. Carey is a 51 year old route salesman in Colorado. A May 2015 letter from his cardiologist reports that Mr. Carey’s ICD “was implanted in March 2009 after he experienced a ventricular fibrillation arrest”. “Since that incident, his defibrillator has never gone off and he’s had no progression of coronary disease”. Recent echocardiography shows “improved ventricular function with an EF of 40-50%”. “Mr. Carey is active without limitations without angina, heart failure, or arrhythmia symptoms”. “The patient is clear to receive a CDL license from my standpoint. I see no issues with him driving commercial vehicles.”

Martin Carter

Mr. Carter is a 47 year old Class A CDL holder in Maine. A March 11, 2015 letter from his cardiologist reports that Mr. Carter underwent ICD implantation on 4/1/2011. "At the time of the ICD placement, his ejection fraction was between 30-35%". His cardiologists note that "since that time, the patient has gotten progressively stronger". "Ejection fraction 10/5/2012 was 37% and 11/26/13 was 44%". "The patient had a stress test 11/26/2013 which showed no inducible myocardial ischemia". "In a patient such as this, the ICD would never have been considered for implantation". "His ICD has never discharged and he has been followed regularly". "The patient's cardiovascular status has recovered to the point that the ICD is no longer medically necessary but no cardiologist is willing to remove the device". "It is my medical opinion that the patient has recovered sufficiently from his ischemic cardiomyopathy that he no longer meets the restriction of ejection fraction less than 40% limiting his ability to drive. I would ask that he be considered for reinstatement of commercial tractor-trailer license". "Prior to the placement of his ICD, Mr. Carter was treated medically and surgically and responded well". "He had a near syncopal episode on 3/2/2010 felt to be secondary to excessive medication and dehydration. He has had no recurrences since that time."

Carl Jeglum

Mr. Jeglum is a 58 year old Class A CDL holder in Washington. An October 22, 2015 letter from his cardiologist reports that in "March of 2005, (Mr. Jeglum) had an Internal Cardiac Defibrillator placed." "Since then his implantable device has been checked frequently and has remained stable without further incident." "The device has never been discharged or deployed since the time he has had the device in place." "He has not had any ongoing cardiac symptoms and in my opinion is fully capable of performing his usual duties as a driver as per the guidelines

for the Department of Transportation.” Mr. Jeglum writes, “I already have a intrastate waiver with no problems in the past 10 years.”

William Kastner

Mr. Kastner is a 61 year old CDL holder in New Jersey. A May 2015 letter from his cardiologist reports that Mr. Kastner’s defibrillator “was implanted in 2006 after he experienced a myocardial infarction resulting in reduced left ventricular ejection fraction”. His cardiologist notes that “Mr. Kastner has never had an episode of syncope, symptomatic palpitations, loss of consciousness, cardiac arrest, documented ventricular tachycardia or ventricular fibrillation.” His electrophysiology group has recommended “that it is safe for him to continue to ride his motorcycle, and he has had no adverse events or effects from this”. He is followed regularly by his electrophysiologist office and has no untoward events with his defibrillator. “He has never had any syncope, palpitations, or discharges from his cardiac defibrillator.”

Mark Todd Smith

Mr. Smith is a 52 year old class A-CDL holder in Georgia. Medical documentation from his cardiologist between 2013 and June 2015 reports that he was upgraded from a dual chamber ICD to a biventricular ICD for ventricular arrhythmias. Mr. Smith had a pulmonary valve replacement in 2015. A September 2015 report from his cardiologist states “he has no complaints of PND (paroxysmal nocturnal dyspnea), orthopnea, LE (lower extremity) edema, syncope, or pre-syncope”. An October 2015 letter from his cardiologist reports that his ICD has “shown normal function”. “He also uses it as a pacemaker.” “Since 2014, he has not had ICD therapy because he underwent a procedure to correct that problem”. “Considering his cardiac issues, he is safer to drive professionally now than he ever has been.”

Andre Williams

Mr. Williams is a 57 year old CDL holder in Georgia. An August 2015 letter from his cardiologist reports that Mr. Williams's ICD was implanted in February 2013. "His ICD has been checked every 6 months and has not fired/deployed". "He has done well with no ICD shocks".

Request for Comments

In accordance with 49 U.S.C. 31315 and 31136(e), FMCSA requests public comment from all interested persons on the exemption applications described in this notice. We will consider all comments received before the close of business on the closing date indicated earlier in the notice.

Issued on: November 13, 2015.

Larry W. Minor
Associate Administrator for Policy

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